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- · Review the responsibilities of the pharmacist-in-
- · Review the most common deficiencies found during inspections of Class C pharmacies.



· To promote, preserve, and protect the public health, safety, and welfare by fostering the provision of quality pharmaceutical care to the citizens of Texas, through the regulation of the practice of pharmacy; the operation of pharmacies; and the distribution of prescription drugs in the public interest.



- Texas Pharmacy Act, Occupations Code, $\S\S\,551-566,\,568-569$ Texas Pharmacy Rules
- Chapter 281. Administrative Practice and Procedure
- Chapter 283. Licensing Requirements for Pharmacists Chapter 291. Pharmacies

- Chapter 295. Pharmacists
 Chapter 297. Pharmacy Technicians and Pharmacy Technician Trainees
- Chapter 303. Destruction of Dangerous Drugs and Controlled Substances
- Chapter 309. Generic Substitution
- Chapter 311, Code of Conduct Texas Controlled Substances Act and Rules
- Texas Dangerous Drug Act Texas Food, Drug and Cosmetic Act



- Each institutional pharmacy in a facility with 101 beds or more shall have one full-time pharmacist-in-charge, who may be pharmacist-in-charge for only one such pharmacy.
- However, a pharmacist-in-charge may be in charge of one facility with 101 beds or more and one facility with 100 beds or less, including a rural hospital, provided the total number of beds does not exceed 150 beds.



 Each institutional pharmacy in a facility with 100 beds or less shall have one pharmacist-in-charge who is employed or under contract, at least on a consulting or part-time basis, but may be employed on a full-time basis, if desired, and who may be pharmacist-in-charge for no more than three facilities or 150 beds.



- The consultant pharmacist may be the pharmacist-inpharmac
- If the pharmacist-in-charge is employed on a consulting basis, a written agreement shall exist between the facility and the pharmacist, and a copy of the written agreement shall be made available to the board upon request.



- Effective Date: December 7, 2014
- Number of beds The total number of beds is determined by the number of:
 - Beds that the hospital is licensed for by the Texas Department of State Health Services; or
 - Inpatients admitted during the previous calendar year divided by 365 (or 366 if the previous calendar year is a leap year).



 A pharmacist shall be accessible at all times to respond to other health professional's questions and needs. Such access may be through a telephone which is answered 24 hours a day, (e.g., answering or paging service), a list of phone numbers where the pharmacist may be reached, or any other system which accomplishes this purpose.



Responsibilities of the PIC



- Pharmacy technicians and pharmacy technician trainees must be registered BEFORE they begin work in the pharmacy.
- In addition, pharmacy technicians must renew that registration every 2-years and <u>CANNOT</u> work with a delinquent registration.

Education and Training of Pharmacy
Technicians and Pharmacy Technician Trainees

- Pharmacy technicians and pharmacy technician trainees shall complete initial training as outlined by the pharmacist-in-charge in a training manual.
- This training may not be transferred to another pharmacy unless:
 - the pharmacies are under common ownership and control and have a common training program; and
 - the pharmacist-in-charge of each pharmacy in which the pharmacy technician or pharmacy technician trainee works certifies that the pharmacy technician or pharmacy technician trainee is competent to perform the duties assigned in that pharmacy.

Education and Training of Pharmacy
Technicians and Pharmacy Technician Trainees

- The pharmacist-in-charge shall assure the continuing competency of pharmacy technicians and pharmacy technician trainees through in-service education and training to supplement initial training.
- The pharmacist-in-charge shall document the completion of the training program and certify the competency of pharmacy technicians and pharmacy technician trainees completing the training.

Texas State Board of Pharmacy Class C Pharmacist-in-Charge Training



· A written record of initial and in-service training of pharmacy

technicians/trainees shall be maintained and contain the following information:

- name of the person receiving the training;
- date(s) of the training;
- general description of the topics covered;
- a statement that certifies that the pharmacy technician/trainee is competent to perform the duties assigned;
- name of the person supervising the training; and
- signature of the pharmacy technician/trainee and the pharmacist-in-charge or other pharmacist employed by the pharmacy and designated by the pharmacist-in-charge as responsible for training of pharmacy technicians/trainees



- · Pharmacy technician/trainee training shall be outlined in a training manual.
- Such training manual shall, at a minimum, contain the following:
 - written procedures and guidelines for the use and supervision of pharmacy technicians/trainees. Such procedures and guidelines shall:
 - specify the manner in which the pharmacist responsible for the supervision of pharmacy technicians and pharmacy technician trainees will supervise such personnel and verify the accuracy and completeness of all acts, tasks, and functions performed by such personnel; and
 - specify duties which may and may not be performed by pharmacy technicians and pharmacy technician trainees;



- instruction in the following areas and any additional areas appropriate to the duties of pharmacy technicians/trainees in the pharmacy:
 - Orientation;
 - Job descriptions;
 - Communication techniques;
 - Laws and rules:
 - Security and safety;
 - Prescription drugs:
 - Basic pharmaceutical nomenclature;
 - · Dosage forms;

Education and Training of Pharmacy Technicians and Pharmacy Technician Trainees

- Drug orders:
 - · Prescribers;
 - · Directions for use;
 - · Commonly-used abbreviations and symbols;
 - · Number of dosage units;
 - · Strengths and systems of measurement;
 - · Routes of administration;
 - · Frequency of administration; and
 - · Interpreting directions for use;

Education and Training of Pharmacy Technicians and Pharmacy Technician Trainees

- Drug order preparation:
 - · Creating or updating patient medication records;
 - Entering drug order information into the computer or typing the label in a manual system;
 - · Selecting the correct stock bottle;
 - Accurately counting or pouring the appropriate quantity of drug product;
 - Selecting the proper container;
 - · Affixing the prescription label;
 - · Affixing auxiliary labels, if indicated; and
 - Preparing the finished product for inspection and final check by pharmacists;

Education and Training of Pharmacy Technicians and Pharmacy Technician Trainees

- · Other functions;
- · Drug product prepackaging;
- Written policy and guidelines for use of and supervision of pharmacy technicians and pharmacy technician trainees;
- · Confidential patient medication records; and
- Pharmacy technicians/trainees compounding non-sterile and/or sterile preparations shall meet the training and education requirements specified in §291.131 (regarding Pharmacies Compounding Non-sterile Preparations) and §291.133 (regarding Pharmacies Compounding Sterile Preparations)



 Ensuring that drugs and/or devices are prepared for distribution safely, and accurately as prescribed



 Supervising a system to assure maintenance of effective controls against the theft or diversion of prescription drugs, and records for such drugs.



- The institutional pharmacy shall be enclosed and capable of being locked by key, combination, or other mechanical or electronic means, so as to prohibit access by unauthorized individuals. Only individuals authorized by the pharmacist-in-charge shall enter the pharmacy
- Each pharmacist on duty shall be responsible for the security of the institutional pharmacy, including provisions for adequate safeguards against theft or diversion of dangerous drugs, controlled substances, and records for such drugs.
- The institutional pharmacy shall have locked storage for Schedule II controlled substances and other drugs requiring additional security.



- The theft or significant loss of any controlled substance by a pharmacy must be reported in writing to the Board immediately upon discovery. This information may be submitted on a copy of the Drug Enforcement Administration (DEA) report of theft or loss of controlled substances, DEA Form 106, or by submitting a list of all controlled substances stolen or lost.
- In addition, a pharmacy shall report in writing to the Board immediately upon discovery, the theft or significant loss of any dangerous (non-controlled) drug by submitting a list of the name and quantity of all dangerous drugs stolen or lost.

Data Processing System

- The pharmacist-in-charge shall report to the board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss.
- The pharmacy shall maintain a backup copy of information stored in the data processing system to assure that data is not lost due to system failure.
- A pharmacy that changes or discontinues the use of a data processing system must transfer the records of dispensing to the new data processing system or purge the records of dispensing to a printout which contains the same information required on the daily printout.



 Participating in the development of a formulary for the facility, subject to approval of the appropriate committee of the facility.



 Assuring that the pharmacy maintains and makes available a sufficient inventory of antidotes and other emergency drugs as well as current antidote information, telephone numbers of regional poison control centers and other emergency assistance organizations, and such other materials and information as may be deemed necessary by the appropriate committee of the facility.



- A reference library shall be maintained that includes the following in hard-copy or electronic format and that pharmacy personnel shall be capable of accessing at all times:
 - current copies of the following:
 - Texas Pharmacy Act and rules;
 - Texas Dangerous Drug Act and rules;
 - · Texas Controlled Substances Act and regulations; and
 - Federal Controlled Substances Act and regulations (or official publication describing the requirements of the Federal Controlled Substances Act and regulations);



- at least one current or updated reference from each of the following categories:
 - drug interactions. A reference text on drug interactions, such as Drug Interaction Facts. A separate reference is not required if other references maintained by the pharmacy contain drug interaction information including information needed to determine severity or significance of the interaction and appropriate recommendations or actions to be taken;
 - a general information reference text, such as:



- Facts and Comparisons with current supplements;
- United States Pharmacopeia Dispensing Information Volume I (Drug Information for the Healthcare Provider);
- AHFS Drug Information with current supplements;
- Remington's Pharmaceutical Sciences; or
- Clinical Pharmacology;



- a current or updated reference on injectable drug products, such as Handbook of Injectable Drugs;
- basic antidote information and the telephone number of the nearest regional poison control center;
- metric-apothecary weight and measure conversion charts.



 Maintaining records of all transactions of the institutional pharmacy as may be required by applicable law, state and federal, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials including pharmaceuticals, components used in the compounding of preparations, and participate in policy decisions regarding prescription drug delivery devices.

Maintaining Records of all Transactions of the Pharmacy

- · §291.75 regarding Records
 - Every record must be kept by the pharmacy for at least 2 years from the date of the record and be available to the Texas State Board of Pharmacy within 72 hours if requested.
 - Records of Schedule II controlled substances shall be maintained separately.
 - Records of Schedule III V controlled substances shall be maintained separately or readily retrievable from all other records of the pharmacy.



- · Inventory Records
 - The PIC is responsible for taking an initial inventory on the opening day of business; however, the PIC may delegate this to another individual.
 - The inventory must include all controlled substances.



- · Change of PIC
 - When a change of PIC of a pharmacy occurs, the required inventory must be taken on the date of the change.
 - The PIC must notify the Board that a change of PIC has occurred and that the inventory was taken.
 - This information must be reported to the Board within 10 days.



 Required change of PIC inventory includes all controlled substances.

Maintaining Records of all Transactions of the Pharmacy

 An annual inventory must be taken on May 1 of each year or on the pharmacy's general physical inventory date. The inventory may be taken within 4 days of the specified inventory date and must include all controlled substances. The inventory must be signed by the PIC and notarized within 3 days, excluding Saturdays, Sundays, and federal holidays, of completing the inventory.

Maintaining Records of all Transactions of the Pharmacy

 Inventories must be filed separately from all other records in the pharmacy and be available for inspection by the Board for 2 years.



 Assuring that records in a data processing system are maintained such that the data processing system is in compliance with Class C pharmacy requirements.



 Assuring that a reasonable effort is made to obtain, record, and maintain patient medication records.



 Assuring the legal operation of the pharmacy, including meeting all inspection and other requirements of all state and federal laws or rules governing the practice of pharmacy.



- A pharmacy must open and be in operation with a sufficient number of transactions within 6 months of the of issuance of the pharmacy's license.
- Inspections
 - The Texas Pharmacy Act, Chapter 556, authorizes the Board to enter and inspect pharmacies.
 - The Board agent will state the purpose of the inspection, present appropriate credentials, and a written notice of the authority for inspection.
 - It is grounds for discipline of a pharmacist's license for obstructing a Board agent in the lawful performance of duties of enforcing the Act.



- When a pharmacy closes, the pharmacist-in-charge (PIC) shall forward to the Board, within 10 days, the following items:
 - written notice of the closing which includes the actual date of closing;
 - pharmacy license;
 - statement attesting that the required inventory has been conducted and the manner by which the drugs possessed by the pharmacy were transferred or disposed; and
 - location of all records belonging to the pharmacy 9e.g., if prescription records were transferred to another pharmacy, give name and address of pharmacy.



- Any drug or device bearing an expiration date shall not be dispensed beyond the expiration date of the drug or device
 - Outdated drugs or devices shall be removed from dispensing stock and shall be quarantined together until such drugs or devices are disposed of properly.
- Class C Pharmacies may not sell, purchase, trade or possess prescription drug samples.



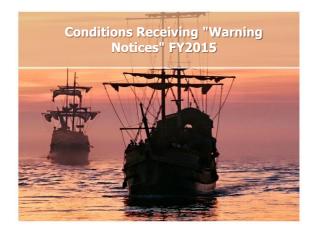
- Chapter 303 outlines the requirements for the destruction of dangerous drugs and controlled substances.
- A pharmacy may accept controlled substances that have been previously dispensed to a patient as allowed by federal laws of the Drug Enforcement Administration (DEA).

DEA Regulations on Disposal of Controlled Substance

- · Effective Date: October 9, 2014.
- Authorizes certain DEA registrants, <u>including pharmacies</u> to become <u>authorized</u> collectors (Note: this will require modification of the DEA registration to obtain authorization to be a collector).
- Authorizes pharmacies to operate collection receptacles at long-term care facilities.



- Prescription drugs and devices shall be stored within the prescription department or a locked storage area.
- All drugs shall be stored at the proper temperatures as defined in the USP/NF.
- The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs.
- The temperature of the refrigerator shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration.





Class	FY2015	% of FY2015 Inspections
Class A Pharmacies	2,275	76%
Class A-S	144	5%
Class B Pharmacies	5	<1%
Class C Pharmacies	268	9%
Class C-S	128	4%
Class D Pharmacies	95	3%
Class F Pharmacies	61	2%
Class G Pharmacies	15	<1%
Totals	2,991	100%



Class	# Pharmacies Receiving WN	% Receiving WN
Class A	992	77%
Class A-S	84	6%
Class B	2	<1%
Class C	80	6%
Class C-S	87	7%
Class D	31	2%
Class F	17	1%
Class G	0	N/A
Totals	1,293	100%



Violation	Number of WN Issued*	% of Total WN
Records	731	9%
Sterile Preparations	647	29%
Pharmacy Technicians	564	
Drug/Stock Environment	421	14%
Prescriptions	335	9%
Inventory	319	5%
* One pharmacy may receive multiple Warning Notice violations.		

1	Condition	Number of WN Issued	Total
	Records		731
	Records Not Available	314	
	Absence of R.Ph. Record	66	
	Rx Not Separated	17	
	Rx Records Not Numerical Order	25	
	Improper Transfer of RX copies	3	
	Invoices Not Separated/Retrievable	122	
	Records for Non-Sterile Compounds	169	
	No Written Information on RX	10	



Condition	Number of WN Issued	Total
Sterile Preparations		647
No/Incomplete QA/QC	99	
No/Incomplete P&P Manual	237	
No/Inadequate Preparation Area	165	
IV Preparation	131	
No DUR	13	
Cytoxic/Bio Procedures	2	



Condition	Number of WN Issued	Total
Pharmacy Technicians		564
No/Incomplete Training	510	
No/Improper Supervision	19	
Improper Registration	29	
No Name Tags	6	



Condition	Number of WN Issued	Total
Drug Stock/Environment		421
Improper Environment	137	
Out-of-Date Drug Stock	158	
Security	65	
Unsanitary	32	
Improper Drug Storage	20	
Area for Non-Sterile Compounding	7	
Violation of Limited Formulary	2	



Condition	Number of WN Issued	Total
Prescriptions		335
Lack Proper Information	159	
Prescription Label Incorrect	136	
Official Rx Non-Compliance	40	



Condition	Number of WN Issued	Total
Inventory		319
No Annual Inventory	84	
No Change of Ownership Inventory	5	
No Change of PIC Inventory	35	
Incomplete Inventory	194	
Improper Drug Destruction	1	



- Individuals performing technician duties without an active registration.
- Technicians performing technician duties with no pharmacist on site.
- Technicians performing pharmacist-only duties with no pharmacist on site (results in emergency temporary suspension hearing).
- Pharmacists who do not verbally counsel a patient on a new prescription.



- Pharmacy is not able to produce 2 consecutive annual inventories.
- · PIC falsifies response to a Warning Notice.
- Pharmacies dispensing/shipping prescription drugs into other states without holding a pharmacy license in that state.
- Pharmacies compounding sterile preparations without proper licensure (e.g., Class A who should have a Class A-S pharmacy license).



- · Egregious Conditions
 - Dispensing CIIs pursuant to prescriptions not issued on an Official Form;
 - Excessive quantity of out-of-date stock (i.e., more than 25% of the inventory);
 - Pharmacy closed and did not notify TSBP of closing;
 - Operating without a PIC for an extended period of time (i.e., 3 months or more).



- · Continuing threat For example:
 - Impaired pharmacist on duty; or
 - Sterile compounding pharmacies who have extensive non-compliance with Board Rule 291.133 and will not voluntarily agree to "cease and desist" sterile compounding until conditions have been corrected.
- Both of these scenarios would result in an <u>Emergency</u> <u>Temporary Suspension Hearing</u>.





S.B. 195 by Sen. Schwertner

- This bill:
- Moves the Prescription Monitoring Program from the Department of Public Safety (DPS) to the Board of Pharmacy; and
- Eliminates the Texas Controlled Substance Registration program.



Timeline for Transfer of the PMP Program

- November 2015 RFP for the new PMP issued by TSBP.
- January 2016 Appriss selected as the vendor.
- February May 2016 System installation at TSBP.
- May/June 2016 –Testing of program.
- September 1, 2016 NEW PMP goes live.

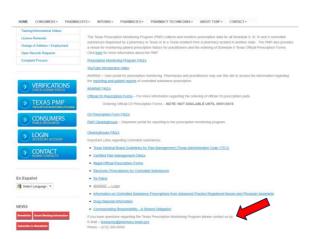






www.facebook.com/TexasPMP/

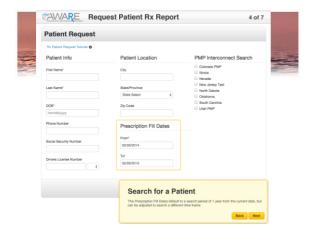
The Texas PMP Facebook page will offer news and updates specific to the program.

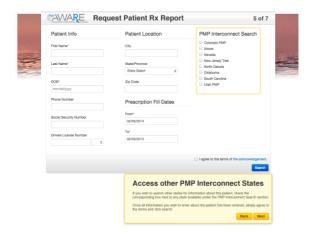


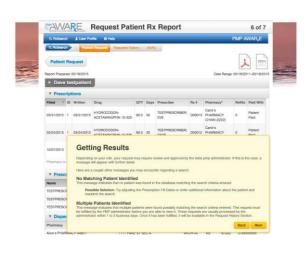














H. B. 1550 by Zerwas/Kolkhorst

- Effective Date: 9/1/2015.
 - Rules adopted by the Board in February 2016.
 - §295.16 Administration of Epinephrine by a Pharmacist.
- · This bill amends the Pharmacy Act to:
 - Allow a pharmacists to administer epinephrine, using an auto-injector, to a patient in an emergency situation.



H. B. 1550 by Zerwas/Kolkhorst (cont.)

- This bill amends the Pharmacy Act to:
 - Specify a pharmacist:
 - May not receive remuneration for the administration of epinephrine but may seek reimbursement for the cost of the epinephrine auto-injector.
 - Who administers epinephrine through an auto-injector device is not liable for civil damages if the pharmacist acts in good faith and complies with Board rules.







- Texas Pharmacy Act, Sec. 551.005. Application of Sunset Act.
 - The Texas State Board of Pharmacy is subject to Chapter 325, Government Code (Texas Sunset Act). <u>Unless continued in existence as provided by that chapter, the board is abolished and this subtitle expires September 1, 2017.</u>



Sunset Review Time Line

- August 2015.
 - TSBP prepares a Self-Evaluation Report.
- October 2015 March 2016.
- Sunset staff reviews the agency.
- · Late March 2016.
 - Sunset's confidential report issued followed by a joint meeting with TSBP to discuss recommendations, followed by Sunset's formal request for agency written response.



Sunset Review Time Line (cont.)

- April 2016
 - Sunset staff report published.
- June 23, 2016
 - Sunset Commission holds a public hearing to receive public comment on the agency.
- Summer 2016.
 - Commission decisions are issued.
- January May 2017.
 - 2017 Legislative Session



Sunset Recommendations

- The Texas State Board of Pharmacy has established itself as a well-run agency capable of effectively responding to new regulatory issues and legislative mandates within its limited resources.
- Absent major problems with the board's basic duties, Sunset staff focused on the prescription drug abuse epidemic facing the country, which claimed 23,000 lives nationally in 2013 and was a constant backdrop to the review.



Sunset Recommendations (cont.)

 Staff closely evaluated the board's new role over the Prescription Monitoring Program, the state's key tool for keeping track of the more than 11 million prescriptions distributed in Texas each year for highly addictive drugs such as Vicodin, Xanax, and OxyContin.



Sunset Recommendations (cont.)

Issue 1 – Key Recommendations

- Beginning in 2018, require pharmacists to search the Prescription Monitoring Program database before dispensing certain controlled substances.
- Require pharmacists to enter dispensing information in the Prescription Monitoring Program database within one business day of dispensing controlled substances.



Sunset Recommendations (cont.)

- Authorize the board to send push notifications and to set related thresholds.
- Direct the board to create delegate accounts for pharmacy technicians, work to integrate the program with pharmacy software systems, and make trend data on dispensing publicly available.



Sunset Recommendations (cont.)

• Issue 2 - Key Recommendations

- Require the board to create a system of graduated penalties for late renewal of pharmacy technician registration.
- Authorize the board to deny renewal applications for licensees and registrants who are noncompliant with an existing board order.
- Direct the board to remove burdensome requirements that pharmacy licensure renewal forms be notarized.
- Direct the board to query a national disciplinary database before license renewal.

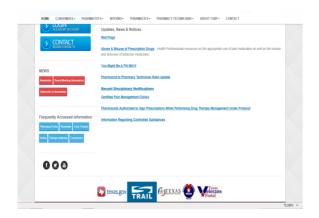


Sunset Recommendations (cont.)

- Issue 3 Key Recommendations
 - Continue the Texas State Board of Pharmacy for 12 years.
 - The board should develop and implement a succession plan to prepare for impending retirements.

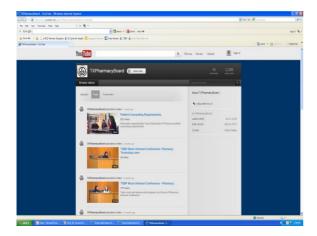














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www.pharmacy.texas.gov





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Thank you for your attendance!

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educationcoordinator@pharmacy.texas.gov